

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

01942-00007

I hereby certify that this correspondence is being transmitted electronically
addressed to "Mail Stop AF, Commissioner for
Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on June 16, 2008

Signature Laurie Hall

Typed or printed name Laurie Hall

Application Number

10/006,796

Filed

December 4, 2001

First Named Inventor

Eija Marjut Pirhonen

Art Unit

1618

Examiner

Micah-Paul Young

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

applicant/inventor.

assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

attorney or agent of record. 34,628
Registration number _____

attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

John P. Iwanicki
Signature

John P. Iwanicki

Typed or printed name

(617) 720-9600

Telephone number

June 16, 2008
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below.

*Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.8. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Eija Marjut Pirhonen, Timo Pohjonen, and) Examiner:)
Jan Nieuwenhuis) Micah-Paul Young)
Serial No.: 10/006,796)
Filed: December 4, 2001) Art Unit: 1618)
Title: BIODEGRADABLE IMPLANT AND) Conf. No.: 9843)
METHOD FOR MANUFACTURING ONE)

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REASONS IN SUPPORT OF REQUEST FOR PRE-APPEAL BRIEF REVIEW

Applicants respectfully request pre-appeal brief review for the following reasons.

I. The Indefiniteness Rejections Should Be Withdrawn

As a housekeeping matter in the present final Office Action dated April 17, 2008, the Examiner has maintained an indefiniteness rejection as to the terms “flexible and rigid” after Applicants had amended the claims in the Office Action Response filed on January 16, 2008 to delete the terms “flexible and rigid.” Applicants request review of the propriety of the indefiniteness rejection.

The Examiner’s rejection of the phrase “a plasticizer dispersed within the rigid matrix only at the surface of the implant” as being contradictory is incorrect. The Examiner believes

that the claim language implies “a complete penetration and distribution of the plasticizer.” However, the plain language of the phrase limits the plasticizer to be within the matrix but only at the surface leaving by implication a core portion that does not include plasticizer. This language clearly excludes prior art embodiments where there is a complete penetration and distribution of the plasticizer. Applicants have provided support in the specification as filed for an implant having a rigid matrix with plasticizer diffused only into its surface and not all the way to its core (see Response dated January 16, 2008, page 6, second paragraph). One of skill in the art would clearly understand the meets and bounds of the invention. Since the claim language is readily understandable to one skilled in the art, the indefiniteness rejection is improper and should be withdrawn.

II. No Restriction Is Warranted

The Examiner incorrectly restricts claims 2 and 9 as being directed to an invention separate from the other claims 1, 3-8, 10-13, and 15-17 requiring a separate search and examination. The Examiner asserts that claims 2 and 9 are directed to an implant that does not include plasticizer as opposed to the remaining claims which comprise plasticizer in the matrix; and claims 2 and 9 are directed to an implant that has a porous surface and a nonporous core as opposed to the remaining claims which comprise an essentially nonporous matrix. However, claim 9 is directed to a method for manufacturing a biodegradable implant having a final step of forming the implant from the mixture of matrix and plasticizer, thus clearly manufacturing an implant that includes plasticizer. Therefore, the Examiner clearly errs in asserting that claim 9 is directed to an implant without plasticizer, and so errs in asserting that claim 9 is directed to a distinct invention from claims 1, 3-8, 10-13, and 15-17.

The Examiner also errs in asserting that claim 2 is directed to a distinct invention from claims 1, 3-8, 10-13, and 15-17. Instead, claim 2 is merely directed to another embodiment of the same inventive implant (see Response dated January 16, 2008, page 8, lines 4-18). An important advantage of the implant of invention is that it has varying physical properties under different conditions. For example, there is a substantial increase in the bending resistance of the implant from before to after it is inserted into an organ system. Claim 2 is directed to the implant and its characteristics after insertion into an organ system, whereas the remaining claims are directed to the implant and its characteristics before insertion into an organ system. Thus, the implant of claim 2 is so related to the implant of the remaining claims as to be an exemplary embodiment and not a distinct invention.

Notwithstanding the arguments above, applicants understand from the present final office action that claims 2 and 9 have been withdrawn.

III. The Examiner Has Not Demonstrated that the Claimed Invention Is Necessarily Present in Niederauer US 6,344,496

In the final Office Action dated April 17, 2008, the pending claims remain rejected under 35 U.S.C. § 102(e) as being anticipated by Niederauer. The Examiner cites col. 9, lines 45-50 of Niederauer for teaching biodegradable films that are soaked in plasticizer until they are malleable enough to conform to any shape required. But the Examiner then makes the leap without any record evidence that the film of Niederauer is soaked in plasticizer only long enough to achieve the claimed structure, that is, to prevent a complete penetration and distribution of the plasticizer throughout the biodegradable film.

The Examiner equates “malleable” with incomplete penetration and distribution of the plasticizer. This technical conclusion of the Examiner as to the teaching of Niederauer is not

based on any explicit teaching of Niederauer as no citation has been provided by the Examiner. No scientific rationale has been provided to support the conclusion that the claimed subject matter is implicit in Niederauer. In fact, the Examiner did not reply to Applicants' arguments to the contrary from pages 10-11 of the Response dated January 16, 2008.

The Examiner's only basis for the present rejection is his own unsupported conclusion that "since the film is only soaked long enough to make it malleable, the plasticizer is not present throughout the matrix." In effect, the Examiner is stating that biodegradable films cannot be made malleable upon complete penetration and distribution of the plasticizer. There is no record evidence for the Examiner's technical conclusion. Without factual evidence that Niederauer soaks his film for a time period to prevent complete penetration and distribution of the plasticizer in a manner to result in the claimed structure, the Examiner cannot maintain the anticipation rejection.

Based on the above, Applicants respectfully request a pre-appeal brief review.

Respectfully submitted,

Dated: June 16, 2008



John P. Iwanicki, Reg. No. 34,628
BANNER & WITCOFF, LTD.
28 State Street, 28th Floor
Boston, MA 02109
Telephone: (617) 720-9600